

## REMARKS

### *Status of the Claims*

With entry of these amendments, claims 1-5 and 8-10 are currently pending and under consideration. Claims 1-5 and 8-10 are currently amended, and claims 6-7 are cancelled. No new matter is added; support for the amendments can be found throughout the application as filed. For example, support for the 16S/23S spacer region can be found on page 12 line 2 of the application as filed, support for one reaction vessel can be found in original claim 7 and on page 11 line 31 and page 19 line 12 of the application as filed, and support for the internal control template can be found on page 18 lines 23-31 and in Example 1 of the application as filed. Other minor amendments were made to correct claim structure and to provide consistent terminology.

### *Claim Objections*

The Examiner has objected to certain informalities in claims 1-10. (Action pages 2-3) Applicants have amended the claims to correct the informalities as suggested by the Examiner. For example, claim 1 now consistently refers to “pathogenic Gram positive bacterium or a subset of pathogenic Gram positive bacteria”, and appropriate italics have been added to designate the bacterial genus and species names.

Applicants respectfully request withdrawal of the objections.

### *Claim Rejections – 35 U.S.C. §112*

The Examiner has rejected claim 3 under 35 U.S.C 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Action page 3) Solely to facilitate prosecution, Applicants have amended claim 3 to spell out the FRET acronym Fluorescence Resonance Energy Transfer.

Applicants respectfully request withdrawal of the 112 rejection of claim 3.

### *Double Patenting*

The Examiner has provisionally rejected claims 1-2 and 6 on the grounds of nonstatutory obviousness-type double patenting over claim 1 of copending Application No. 10/534,915 in view of Jannes et al. Additionally, the Examiner has provisionally rejected claims 1, 4 and 8-9 on the

grounds of nonstatutory obviousness-type double patenting over claims 1 and 6 of copending Application No. 10/532,319.

If a “provisional” double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw the rejections and permit the application to issue as a patent. Application Nos. 10/534,915 and 10/532,319 are not currently allowed. Accordingly, Applicants submit if these provisional rejections are the only outstanding rejections, the present claims should be allowed. However, Applicants will consider filing Terminal Disclaimers when the present claims are indicated as otherwise allowable if/when Application Nos. 10/534,915 and 10/532,319 are allowed.

#### *Claim Rejections – 35 U.S.C. §102*

The Examiner has rejected claim 10 under 35 U.S.C 102(b) as being anticipated by Jannes et al (WO 96/00298). The Examiner asserts in part that Jannes teaches kits for detection of at least one organism from the genera *Staphylococcus*, *Enterococcus* and *Streptococcus*, utilizing 16S-23S spacer region sequences, thereby anticipating each and every limitation set forth in the claim. (Action pages 6-7)

Without acquiescing to the rejection and solely to facilitate prosecution, Applicants have amended claim 10 to additionally require “wherein said amplifying and detecting are performed in one reaction vessel”. Applicants assert that claim 10 as presently amended is not anticipated by Jannes. Jannes teaches method that require multiple reaction step and multiple reaction vessels. See Jannes Examples 1-9 which provide methods for amplification followed by a multi-step membrane-based reverse hybridization assay. In contrast, claim 10 as amended provides for a kit wherein the amplification and detection are performed in one reaction vessel.

Additionally, without acquiescing to the rejection and solely to facilitate prosecution, Applicants have further amended claim 10 to recite “at least one internal control template”. Applicants assert that Jannes does not teach use of an internal control template along with amplification and detection in one reaction vessel.

Because Jannes does not anticipate each every limitation set forth in the claims, for the reasons provided above Applicants respectfully request reconsideration and withdrawal of the §102(b) rejections.

*Claim Rejections – 35 U.S.C. §103*

The Examiner has rejected claims 1-9 under 35 U.S.C 103(a) as being unpatentable over Jannes et al. in view of de Silva et al. (Action page 7) The Examiner asserts, in part, that it would have been *prima facie* obvious to one of ordinary skill in the art to have extended the method taught by Jannes to incorporate the methods of determining and monitoring the temperature dependence of hybridization as taught by de Silva. The Examiner provides that Jannes does not explicitly teach step “bbb” (as amended now “bcb”), and de Silva teaches an embodiment comprising “bbb” (now “bcb”). (Action page 11)

Applicants respectfully submit that the de Silva reference does not correct all of the deficiencies of Jannes. de Silva teaches a method that utilizes 2 hybridization probes + a melting temperature profile for identification of a single base pair change. However, de Silva does not teach the use of an internal control template as required in presently amended claim 1 and in claims dependent upon claim 1. de Silva teaches the amplification and detection of beta-globin sequences as a type of “PCR product quantitation” (de Silva abstract), however this amplification and detection are each performed by an additional set of amplification reagents in a separate reaction vessel than the detection of the primary target of interest (Factor V Leiden) and therefore cannot be considered an internal control template as defined by the instant application (see page 18 lines 23-31 in the application as filed).

Further, the Examiner asserts that it would have been *prima facie* obvious in view of the teaching of de Silva to monitor amplification using melting curve analysis ... and potentially to apply the sequence specific line probes used for detection of the rRNA spacer sequences to the fluorescent FRET format of amplification and detection. (Action page 12) Applicants assert that the probes as provided in Jannes were designed for a different purpose which is inherently different than the function required in a FRET-based system such as taught by de Silva. The Jannes probes were designed for use in a membrane-based hybridization format, and one skilled in the art would appreciate that the probes as provided would not function in a multiplex FRET-based system. For example, the Jannes probes were designed to be immobilized in a line-wise fashion onto a membrane strip (see Jannes Example 1). These immobilized probes do not interact with each other – they are physically separate. In contrast, probes for use in a multiplex FRET-based system would be mixed together in one reaction vessel, along with additional amplification and detection reagents and internal control template. One skilled in the art would instantly appreciate that oligonucleotides together in solution could interact, forming oligo-dimer and secondary structures, all of which could

adversely affect the amplification and detection reactions and result in unpredictable results. Applicants respectfully submit that the Examiner has not established that there would be a reasonable expectation for success in applying the probes of Jannes to the methods of de Silva, and therefore there is no motivation to extend the methods of Jannes in light of de Silva. MPEP 2143.01(v) states “if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (fed Cir. 1984)”.

Because the Examiner has not established a prima facie case of obviousness, for the reasons provided above, Applicants respectfully request the reconsideration and withdrawal of the §103 rejections.

### CONCLUSION

Applicants respectfully assert that the present application is in condition for allowance and request that the Office issue a timely Notice of Allowance. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-730-8566.

Applicants respectfully request a 3-month extension of time to respond to the Office Action mailed March 27, 2008. The response date was June 27, 2008; with the granting of this request, the response time is re-set to September 29, 2008 (September 27, 2008 being a Saturday). The commissioner is hereby authorized to charge the amount of \$1050, the fee due under 37 CFR §1.17(a)(3) to Deposit Account No. 50-0812. Please grant any additional extensions of time that may be required to enter this response and charge any additional fees or credit any overpayments to Deposit Account No. 50-0812.

Please direct all future correspondences to: Customer No. 22829.

Respectfully submitted,

Date: September 29, 2008

By



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